APPENDIX—Continued

| Filing date | Company | Docket No. | Type filing |
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| 12/13/83 | Distrigas of Massachusetts Corp. | RP81-34-006 | Do. |

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## ENVIRONMENTAL PROTECTION AGENCY

[OPTS-59139A; TSH-FRL 2499-2]

### Toxic Substances; Premanufacture Notification Requirements; Approval of Test Marketing Exemptions of Certain Chemicals

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's approval of TME-84-8, TME-84-9, and TME-84-10, three applications for test marketing exemptions (TMEs), under section 5(h)(6) of the Toxic Substances Control Act (TSCA). The test marketing conditions are described below.

**EFFECTIVE DATE:** December 21, 1983.

**FOR FURTHER INFORMATION CONTACT:** Wendy Cleland-Hamnett, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-205, 401 M St. SW., Washington, DC 20460, (202-382-3736).

**SUPPLEMENTARY INFORMATION:** Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and to permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use and disposal of the substances for test marketing purposes will not present any unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities.

EPA has determined that test marketing of the new chemical substances described below, under the conditions set out in the applications, and for the time periods specified below, will not present any unreasonable risk of injury to health or the environment. Production volume, number of workers exposed to the new chemical, and the levels and duration of exposure must not exceed that specified in the applications. All other conditions described in the applications must be met. The following additional restrictions apply: For TME-84-8, the exemption is granted provided that workers are required to wear protective gloves. The Material Safety Data Sheet must include the requirement for workers to wear gloves.

**TME 84-8**

*Date of receipt.*—November 8, 1983.

*Notice of receipt.*—November 18, 1983 (48 FR 52505).

*Applicant.*—METACOMET, Inc.

*Chemical.*—(Generic) Substituted tetrazole.

*Use.*—Photographic ingredient.

*Production volume.*—1-10 kg.

*Number of customers.*—Confidential.

*Worker exposure.*—Dermal exposure from use only for 12 workers.

*Test marketing period.*—1 year.

*Commencing on.*—December 21, 1983.

*Risk assessment.*—Based on analogy with structurally related substances the Agency identified potential health effect concerns. In addition, actual test data showed moderate acute toxicity based on oral exposure. However, worker exposure is expected to be very low and the Material Safety Data Sheet will require workers to wear protective gloves. No environmental releases are expected; therefore, the test market substance should not pose an unreasonable enviornmental risk.

*Public comments.*—None.

**TME 84-9**

*Date of receipt.*—November 8, 1983.

*Notice of receipt.*—November 18, 1983 (48 FR 52505).

*Applicant.*—METACOMET, Inc.

*Chemical.*—(Generic) Substituted benzimidazole/benzoxazole.

*Use.*—Sensitizer for photographic materials.

*Production volume.*—1-10 kg.

*Number of customers.*—Confidential.

*Worker exposure.*—From use only up to 12 workers.

*Test marketing period.*—1 year.

*Commencing on.*—December 21, 1983.

*Risk assessment.*—The test market substance is structurally related to chemicals that exhibit adverse health effects. However, the exposures associated with the test marketing activities are expected to be extremely low. In addition, the substance is not expected to be absorbed through the skin. Although the substance is analogous to substances which exhibit adverse ecological effects, no environmental releases are expected; therefore, environmental risks are insignificant.

*Public comments.*—None.

**TME 84-10**

*Date of receipt.*—November 9, 1983.

*Notice of receipt.*—November 18, 1983 (48 FR 52505).

*Applicant.*—American Hoechst Corporation.

*Chemical.*—Benzenesulfonic acid, 2,4,6-trimethyl, sodium salt.

*Use.*—To produce printing plates containing the diazo.

*Production volume.*—1 kg.

*Number of customers.*—12.

*Exposure information.*—Submitter estimates that during the test marketing period, only one technician will be exposed for one-half hour while weighing the substance before addition to a reaction flask. This will be done under supervision of a chemist. Subsequent handling of the product produced from the TME's substance which contains <0.5% as unreacted impurity was estimated to involve 2 to 3 technicians for a total of less than 1 hour.

*Test marketing period.*—1 Year.

*Commencing on.*—December 21, 1983.

*Risk assessment.*—No significant health or environmental concerns were identified. The estimated worker exposure to the test market substance is expected to be low. In addition due to expected low releases, the test substance should not pose an unreasonable environmental risk.

*Public comments.*—None.

The Agency reserves the right to rescind approval of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present an unreasonable risk to health or the environment.

Dated: December 21, 1983.

**Don R. Clay,**

*Director, Office of Toxic Substances.*

[FR Doc. 83-34497 Filed 12-28-83; 8:45 am]
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[OPTS-42032A; TSH-FRL 2459-3]

### Toxic Substances; Formamide; Decision To Adopt Negotiated Testing Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In response to the Interagency Testing Committee's (ITC) designation of formamide for health effects testing consideration, EPA announced in the Federal Register of May 23, 1983, its preliminary decision not to initiate rulemaking under the Toxic Substances Control Act (TSCA) based on the Agency's tentative

acceptance of a testing program submitted by BASF Wyandotte Corporation. On the basis of its review and consideration of public comments, the Agency finds no reason to alter its preliminary decision. Therefore, for the reasons set forth in both this notice and the Agency's preliminary decision of May 23, 1983, EPA is not proposing a section 4(a) rule to require health effects testing of formamide at this time.

**FOR FURTHER INFORMATION CONTACT:**

Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

**SUPPLEMENTARY INFORMATION:**

## I. Background

EPA issued a notice, published in the **Federal Register** of May 23, 1983 (48 FR 23098), which announced the Agency's preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003; 15 U.S.C. 2601) to require health effects testing of formamide. This decision was based on the Agency's evaluation of the existing data for formamide, the expected exposure profile for formamide and the tentative acceptance of a testing program submitted by the BASF Wyandotte Corporation.

A draft of the BASF proposal was included in the public record (docket number OPTS-42032). The Agency requested comments on both its tentative decision not to require testing of formamide and on the proposed testing scheme.

## II. Summary of Testing Programs

The BASF Wyandotte Corporation proposal consists of a range-finding study followed by a 90-day subchronic study which is designed to characterize the potential subchronic effects of formamide. Because dermal exposure is the most common route of human exposure, the program is designed to clarify the doses at which formamide causes toxic effects after repeated exposure to intact skin over a prolonged period (BASF Wyandotte Corporation, 1982. Proposed voluntary testing program on formamide, November 9, 1982). The study will be performed in male and female Wistar rats, using dermal exposure for 6 hours/day and 5 days/week. The protocols for these studies have been reviewed by EPA scientists and are acceptable. They are available for examination in the public record of this proceeding.

Industry has agreed to begin the range-finding study on or about October 1, 1983. After the range-finding study has been completed, a program review by BASF and EPA personnel will occur to review the data and select doses for the subchronic study. The subchronic phase of testing can be expected to begin by early 1984. The subchronic testing, including histopathology, will be completed in late 1984. An additional 3 months will be required for preparation of the study report and consultation among BASF and EPA scientists. The final report is expected to be submitted to the Agency in early 1985.

## III. EPA's Response to Public Comments

The Agency received comments from the Natural Resources Defense Council (NRDC) on EPA's proposed decision to adopt a negotiated testing program for formamide in lieu of rulemaking to require testing under section 4(a) of TSCA. NRDC expressed a general concern over the Agency's policy of accepting Negotiated Testing Programs in appropriate circumstances. The Agency addressed NRDC's concerns about negotiated testing in previous notices issued in the **Federal Register** of January 5, 1982 (47 FR 335) and July 18, 1983 (48 FR 32730) which discussed the negotiated testing programs for alkyl phthalates and 4-chlorobenzotrifluoride.

The Agency does not agree with NRDC's comment that EPA's experience with negotiated agreements demonstrates a substantial likelihood that industry will not fulfill its testing commitments. While EPA acknowledges that negotiated testing agreements are not legally enforceable, the Agency believes that there are strong practical reasons to expect that, in the vast majority of cases, the companies will live up to their agreement. In the event that this does not occur, the Agency still has the option of issuing a test rule.

The NRDC commented that the public did not have an opportunity to participate in the actual negotiation process for formamide. The EPA believes that the public has been provided sufficient opportunity to comment during the pre-negotiation phase and the post-negotiation phase of this negotiated testing agreement. Also, public comment was solicited before a final determination was made and this final notice was published. NRDC did not choose to participate or attend the public meetings which discussed testing programs for formamide and they did not submit comments on the proposed testing program for formamide.

NRDC also expressed a concern that public access to original data obtained from negotiated testing programs would be limited. EPA does not agree. EPA has the same authority to disclose health and safety data generated from negotiated testing as it would if the testing were conducted under a rule. Section 14(b)(1)(A)(i) makes data from any health and safety study on a chemical in "commercial distribution" (which should include virtually all chemicals designated by the Interagency Testing Committee) releasable on the same basis as does section 14(b)(1)(A)(ii) which relates to data developed as a result of a test rule.

## IV. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 [docket number OPTS-42032]. This record includes:

(1) **Federal Register** notice designating formamide to the priority list and public comments received thereon.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) **Federal Register** notice requesting comment on the negotiated testing proposal and comments received in response thereto.

(6) **Federal Register** notice announcing a final decision to adopt a negotiated testing program.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in Rm. E-107, 401 M St. SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: December 21, 1983.

**William D. Ruckelshaus,**

*Administrator*

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## FEDERAL EMERGENCY MANAGEMENT AGENCY

**[FEMA-3087-EM]**

## Emergency and Related Determinations; Mississippi

**AGENCY:** Federal Emergency Management Agency.